

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO ALL WAVE 2 CASES

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION AND MEMORANDUM TO
LIMIT THE OPINIONS AND TESTIMONY OF TIMOTHY MCKINNEY, M.D.**

Plaintiffs hereby submit their *Reply in Support of Their Motion and Memorandum to Limit the Opinions and Testimony of Timothy McKinney, M.D.* and respectfully show the Court as follows:

I. INTRODUCTION

Defendants, in their Opposition, fundamentally misunderstand Plaintiffs' arguments in support of exclusion of Dr. McKinney's opinions, as evidenced by their assertion: "At bottom, Plaintiffs are challenging Dr. McKinney's conclusions, not his methodology." Defs.' Opp. at 4. Because Plaintiffs are in fact challenging Dr. McKinney's conclusions which are based on unsound methodology, or are irrelevant, speculative or outside his area of expertise, Plaintiffs' arguments are properly presented through a *Daubert* motion; and therefore, Plaintiffs respectfully request the Court grant their Motion.

II. ARGUMENT

A. Dr. McKinney Should Not Be Permitted To Opine On Native Tissue Prolapse Repairs Or The Adverse Events Reported In The Sister Trial.

Defendants argue that Dr. McKinney's "opinions on native tissue prolapse repairs, including his interpretation of the SISTEr clinical trial," Defs. Opp. at 2, are relevant because Dr.

McKinney submitted a “Prolene Soft Report” in both “Wave 1 and Wave 2.” Defs.’ Opp. at 3. Dr. McKinney did submit a “Prolene Soft Report” in both Waves, and Plaintiffs and Defendants have confined their arguments with regard to that report to their Wave 1 briefing. However, this fact does not rebut Plaintiffs’ argument that Dr. McKinney’s arguments related to *native tissue prolapse* repairs are irrelevant to his opinions on Defendants’ TVT and TVT-O products, both of which use synthetic material to treat SUI. Dr. McKinney’s opinions on native tissue prolapse repairs are contained in his expert report on TVT and TVT-O, and therefore, Plaintiffs must assume he intends to use these opinions as a basis for his ultimate conclusion that Defendants’ TVT and TVT-O products are safe. Thus, these opinions remain irrelevant and should be excluded.¹

Moreover, Defendants make no additional argument as to why Dr. McKinney should not be allowed to opine on the adverse events reported in the SISTEr trial. *See* Defs.’ Opp. at 3. Plaintiffs argue that because the SISTEr trial studied adverse events related to procedures that only utilized natural tissue, these results are irrelevant to Dr. McKinney’s opinions on Defendants’ synthetic slings. Because Defendants presented no substantive argument in opposition, and for the reasons more fully stated in Plaintiffs’ Motion, these opinions should be excluded.

B. Dr. McKinney Should Not Be Permitted To Opine On Either The 2015 Cochrane Review Or The Nilsson Study.

Here, Defendants misinterpret Plaintiffs’ arguments as disagreeing with Dr. McKinney’s conclusions rather than attacking the methodology underlying those conclusions. It is proper

¹ As a practical matter, excluding these opinions by way of Plaintiffs’ Motion will be beneficial at trial because Defendants will be prevented from confusing the jury by presenting intertwined expert testimony on prolapse and SUI products. Additionally, it will prevent additional briefing as Plaintiffs will not need to file a motion *in limine* on this issue.

under a *Daubert* analysis for the Court to exclude the opinions of an expert if they are not based upon sound methodology or reliable application of sound methodology. *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). Here, Plaintiffs make just such an argument. *See* Pls.’ Mot. at 6-9 (challenging Dr. McKinney’s reliance on the 2015 Cochrane review based on his understanding of it as one of the “highest levels of evidence,” when in fact the authors of the review stated the results were based on “moderate quality evidence;” arguing that the 2015 Cochrane Review compared *methods* not products, and therefore, the results are not relevant to the safety of Defendants’ products; and challenging Dr. McKinney’s reliance on the Nilsson study as that study was conducted in Europe *prior* to Defendants’ products being introduced in the United States and the physicians involved in the study utilized a *different procedure* for implantation than doctors utilize in the United States). Defendants urge the Court to refrain from looking closely at Dr. McKinney’s methodology and application of methodology because in so doing, it becomes apparent that Dr. McKinney’s reliance on the 2015 Cochrane Review and the Nilsson study do not provide sound bases for Dr. McKinney’s safety and efficacy opinions. For these reasons, and those reasons stated in Plaintiffs’ Motion, Defendants’ arguments should be rejected.

Moreover, Defendants’ authority cited in support of their arguments in this regard is not helpful, likely, in part, due to Defendants’ misunderstanding of the substance of Plaintiffs’ arguments. Defendants cite *Hovey v. Cook* for the proposition that: “even if the medical literature is ‘not seamlessly align[ed]’ with an expert’s interpretation of a study, his methodology is not rendered unreliable as long as his *interpretation is plausible*.” Defs.’ Opp. at 3 (emphasis added). In *Hovey v. Cook*, the Court did not exclude an expert’s opinions based on the grounds that it lacked a reliable basis because: “Cook’s interpretation of these articles as unrelated to excessive

inflammation [was], to put it mildly, subject to debate.” 2015 WL 1405565, at *5 (S.D. W. Va. Mar. 26, 2015). Several of the articles cited by the expert were not only written by the expert himself, but also reported findings of “excessive inflammation.” *Id.* Here, the basis for Dr. McKinney’s opinions is not “subject to debate.” The basis for Dr. McKinney’s opinions on the safety of Defendants’ products, the 2015 Cochrane Review and the Nilsson study, do not bridge the “analytical gap between the data and the opinion,” *Id.* (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997), for the reasons stated herein and in Plaintiffs’ Motion; and therefore, his opinions on these matters should be excluded.

C. Dr. McKinney’s Opinions Regarding “Lowest Level Of Evidence,” The “Gold Standard,” And “Escape From The Dark Ages” Are Not Taken Out Of Context And Should Be Excluded.

Defendants’ primary argument against exclusion of Dr. McKinney’s opinions that Plaintiffs’ experts relied on the “lowest level of evidence,” that Defendants’ products represent the “Gold Standard,” and that Defendants’ products represent an “escape from the dark ages” is that Plaintiffs took these statements out of context. However, Defendants’ argument is wholly conclusory as it does not explain *how* these statements were taken out of context. These statements are contained in Dr. McKinney’s expert report and were placed in the context that Dr. McKinney chose. Defendants’ citation to *Trevino v. Boston Sci. Corp.* is misplaced as in the portion of that case cited by Defendants, the Court was admonishing all parties for “regularly present[ing] out-of-context statements, after-the-fact rationalization of opinions, and incomplete deposition transcripts,” among other issues, thereby “creat[ing] the perfect storm of obfuscation.” 2016 WL 2939521, at *1 (S.D. W. Va. May 19, 2016). Thus, Defendants’ argument is an express assertion that Plaintiffs’ argument is improperly presented for the purpose of obfuscation. While this represents a serious allegation of improper litigation conduct, Plaintiffs presume this

argument is the product of hyperbole. If Defendants desire to present this argument, they should, at the very least, describe how Dr. McKinney's opinions were taken out of context, and as they have not, Defendants' arguments should be rejected.

Rather, Dr. McKinney has opined that Plaintiffs' experts rely on "lowest level of evidence" without pointing to a single shred of evidence that Dr. McKinney believes is of poor quality. As such, Dr. McKinney's opinion is unsupported and should be excluded. Defendants' argument that there is, generally speaking, a "hierarchy of scientific evidence," Defs.' Opp. at 5, does nothing to change this fact. With regard to Dr. McKinney's "Gold Standard" statement, Defendants argue this statement is not unsupported by directing the Court and Plaintiffs to a section of Dr. McKinney's expert report that refers to Defendants' products as the "Gold Standard" *without* citation to any source. Defs. Opp. at 5-6. When looking at Defendants' cited portion of the expert report, Dr. McKinney refers to Defendants' products as the "Gold Standard" and follows this statement with various statistics, all of which are not cited. Ex. B at 7 (first full paragraph). Then Dr. McKinney states that Defendants' products have been studied by various pertinent "medical and surgical organizations" and follows that statement with another repetition that Defendants' products are "widely recognized as the Gold Standard," again, with no citation to authority. Ex. B at 7-8. As such, Dr. McKinney's opinions in this regard should be excluded. Additionally, Defendants make no argument in opposition to Plaintiff's assertion that Dr. McKinney's statement that Defendants' products "represent an escape from the dark ages" is improperly prejudicial, and therefore, this opinion should also be excluded.

D. All Speculative Opinions, Or Those Unsupported By The Medical Literature Or Dr. McKinney's Experience, Should Be Excluded.

First, Defendants argue that Dr. McKinney's experience provides a basis for his knowledge as to what the "frustration" of all surgeons was "among those in his field." Defs.'

Opp. at 6-7. Defendants gloss over the fact that Plaintiffs' issue with Dr. McKinney's opinion is that he stated all surgeons were frustrated in that "native tissue [repairs] . . . had an unacceptable failure rate." Pls.' Mot. at 10. If Dr. McKinney is going to be allowed to opine on the frustration of *all* of his colleagues' frustrations with the failure rate of native tissue repairs, then he should be required to provide some basis for this opinion. As discussed above, Dr. McKinney opines on native tissue *prolapse* repairs, but these opinions are irrelevant to Defendants' TVT and TVT-O products.

Second, Defendants respond to Plaintiffs' argument regarding Dr. McKinney's opinion that surgery for SUI has been shown to be "most definitive treatment" by arguing that this statement is not vague or ambiguous because it is taken out of context. Defendants go on to state that Dr. McKinney's statement is not a "per se 'opinion' . . . [rather] it gives background for the opinions ultimately expressed." Defs. Opp. at 7. While Plaintiffs still read Dr. McKinney's statement as an opinion, albeit an unclear opinion, as Defendants are only proffering this opinion as "background for the opinions ultimately expressed," then Plaintiffs' objection is withdrawn, subject to reservation of the right to object to the expression of this opinion at trial.

Third, Defendants' response regarding Dr. McKinney's opinion that Defendants' TVT products have the "longest and broadest track record of safe and effective use" simply restates their misunderstanding of Plaintiffs' prior arguments. Defendants argue: "these criticisms go to Dr. McKinney's conclusion—not his methodology—which is not a proper basis for exclusion." Defs.' Opp. at 7. As already explained above, Defendants' assertion misunderstands the substance of Plaintiffs' argument as Plaintiffs do in fact attack the methodology of Dr. McKinney's safety and efficacy opinions; and therefore, his opinions in this regard should be excluded.

Finally, Defendants argue that Dr. McKinney's pore size opinion is supported if one gives Dr. McKinney's deposition a "complete reading." Defs.' Opp. at 8. However, when one fully reads the portion of Dr. McKinney's deposition cited by Defendants it reveals that Dr. McKinney relied upon: (1) an irrelevant study related to hernia mesh; (2) that he "think[s] [he] talked a little bit more about like a Falconer study (where Dr. McKinney does cite Falconer in his expert report, it is not in support of pore size);" and (3) that he did not even search for material specific to vaginal mesh pore size in forming his opinions. *See* Ex. D at 32:16-35:1. Despite Defendants' assertion to the contrary, Dr. McKinney's opinion on pore size is not supported by any reliable basis and should be excluded.

E. Dr. McKinney's Opinions On The Adequacy Of Defendants' IFU Should Be Excluded.

Plaintiffs argue in their Motion that Dr. McKinney's deposition testimony demonstrates that he intends to opine on the adequacy of Defendants' IFU.² While Plaintiffs maintain that Dr. McKinney's testimony clearly demonstrates an opinion on adequacy, Defendants have taken the position that: "Dr. McKinney's IFU testimony challenged by Plaintiffs is not an "adequacy" opinion at all much less an opinion on whether the IFUs at issue here, in particular, are adequate." Defs.' Opp. at 8. If Defendants only intend for Dr. McKinney to opine on the "basic premise' of IFUs in general and how physicians in general use and rely on a products IFU," Defs.' Opp. at 9, then Plaintiffs have no objection to this testimony.

F. Dr. McKinney Will Not Opine On The Section 510(K) Process.

² Defendants make much of the fact that Dr. McKinney's IFU testimony was "elicited by Plaintiffs' counsel." Defs.' Opp. at 8. It is unclear why Defendants are implying that it was improper for Plaintiffs' counsel to probe Dr. McKinney, during deposition, as to his opinions that he may offer at trial, and as such, Defendants' observation as to how this testimony was "elicited" is irrelevant to a *Daubert* analysis.

Defendants have indicated that: “Ethicon will not be offering these plaintiff-initiated opinions; thus, Plaintiffs’ request for their exclusion is moot.”³ Defs.’ Opp. at 9. As Defendants expressly stated that Dr. McKinney will not opine on the Section 510(k) process, Plaintiffs agree that this request for exclusion is now moot.

III. CONCLUSION

For the reasons stated in Plaintiffs’ Motion, and more fully explained herein, Plaintiffs respectfully request their Motion be granted in its entirety, except that Plaintiffs’ requests for exclusion regarding Dr. McKinney’s opinions on: (1) the “most definitive treatment;” (2) the adequacy of Defendants’ IFU; and (3) the Section 510(k) process are withdrawn, subject to Defendants’ characterization of such opinions.

Dated: August 18, 2016

Respectfully submitted,

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³ See n.2.

CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2016 a true and correct copy of **Plaintiffs' Reply In Support Of Their Motion And Memorandum To Limit The Opinions And Testimony Of Timothy McKinney, M.D.** was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

Dated: August 18, 2016

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